SLOVENSKI STANDARD

SIST EN ISO 10524-2:2006

01-julij-2006

Nadomeġļa:

SIST EN 738-2:2000

Tlaļni regulatorji za medicinske pline - 2. del: Tlaļni regulatorji v razdelilnikih in ceveh (ISO 10524-2:2005)

Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 2: Hauptstellendruckregler und Leitungsdruckminderer (ISO 10524-2:2005)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 2: Détendeurs de rampes et de canalisations (ISO 10524-2:2005)

Ta slovenski standard je istoveten z: **EN ISO 10524-2:2006**

ICS:

11.040.10

23.060.40

SIST EN ISO 10524-2:2006 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10524-2

April 2006

ICS 11.040.10

Supersedes EN 738-2:1998

English Version

Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 2: Détendeurs de rampes et de canalisations (ISO 10524-2:2005)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 2: Hauptstellendruckregler und Leitungsdruckminderer (ISO 10524-2:2005)

This European Standard was approved by CEN on 20 March 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 10524-2:2006: E

Contents

Page

Foreword

The text of ISO 10524-2:2005 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10524-2:2006 by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2006, and conflicting national standards shall be withdrawn at the latest by October 2006.

This document supersedes EN 738-2: 1998.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 10524-2:2005 has been approved by CEN as EN ISO 10524-2:2006 without any modifications.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC Medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC Medical devices

Clause(s)/sub-clause(s) of this EN	Essential requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5	1	
5.1	2, 6	
5.2	2	
5.3	2	
5.3.1	7.1, 7.3, 9.3	
5.3.2	4, 7.1, 9.2	
5.3.3	3, 5	
5.3.4	7.1, 7.2	
5.4	2, 3, 4	
5.4.1.1	10	
5.4.1.3	10.2	
5.4.2.	12.7.1	
5.4.3	7.2, 7.6	
5.4.4	9.2	
5.4.5.1	9.1, 12.7.4	
5.4.5.2	9.1, 12.7.4	
5.4.5.3	7.5	
5.4.5.4	3	
5.4.5.5	7.5, 9.2, 12.7.1	
5.4.5.6	7.3, 9.3	
5.4.6.1	9.1, 12.7.4	
5.4.6.2	9.1, 12.7.4	
5.4.6.3	7.5	

Clause(s)/sub-clause(s) of this EN	Essential requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.4.6.4	3	
5.4.6.5	7.3, 9.3	
5.5.1	7.2, 9.3	
5.5.2	7.2, 9.3	
6	3, 7.5, 9.2, 9.3, 12.8.1, 12.8.2	
7.1	13.1, 13.2	
7.1.2, a)	13.1, 13.3 a)	
7.1.2, b)	13.3 b)	
7.1.2, c)	13.3 d)	
7.1.3, a)	13.1, 13.3 a)	
7.2	13.2	
7.3	3, 5	
7.3.1	5, 7.2, 7.6	
7.3.2	13.1, 13.3 b)	
8.1	13.1, 13.3 a, 13.4, 13.6 a)	
8.2	9.1, 9.2, 9.3, 13.1, 13.6 c), 13.6 d), 13.6 k)	
8.3	13.6 b)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 10524-2

First edition
2005-05-01

Pressure regulators for use with medical gases —

Part 2: Manifold and line pressure regulators

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 2: Détendeurs de rampes et de canalisations

Reference number
ISO 10524-2:2005(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10524-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

ISO 10524 consists of the following parts, under the general title *Pressure regulators for use with medical gases*:

— *Part 1: Pressure regulators and pressure regulators with flow-metering devices*

— *Part 2: Manifold and line pressure regulators*

— *Part 3: Pressure regulators integrated with cylinder valves*

— *Part 4: Low-pressure regulators*

Introduction

Manifold pressure regulators are used to reduce cylinder pressure to a lower pressure within a source of supply of a medical gas pipeline system.

Line pressure regulators are used to reduce the pressure supplied by manifold pressure regulators or by cryogenic vessels to the lower pressure required at the terminal units of medical gas pipeline systems.

These functions cover a wide range of inlet and outlet pressures and flows which require specific design characteristics.

It is important that the operating characteristics of manifold and line pressure regulators are specified and tested in a defined manner.

It is essential that regular inspection and maintenance be undertaken to ensure that the pressure regulators continue to meet the requirements of this part of ISO 10524.

This part of ISO 10524 pays particular attention to:

— use of suitable materials;

— safety (mechanical strength, leakage, safe relief of excess pressure and resistance to ignition);

— cleanliness;

— type testing;

— marking;

— information supplied by the manufacturer.

Annex B contains rationale statements for some of the requirements of this part of ISO 10524. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this part of ISO 10524. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 10524, but will expedite any subsequent revisions.